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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,113	05/22/2007	Jon Lundberg	11709-006-999	1236

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YOUNG & THOMPSON
209 Madison Street
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EXAMINER

LANDRY II, GERALD ERNEST

ART UNIT	PAPER NUMBER
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3763

NOTIFICATION DATE	DELIVERY MODE
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05/19/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No. 10/583,113	Applicant(s) LUNDBERG ET AL.	
	Examiner GERALD LANDRY II	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-101 is/are pending in the application.
- 4a) Of the above claim(s) 68-94 and 98-100 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-67, 95-97, 101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

The Examiner notes an error in the restriction requirement dated 05/15/2009. Group I should correctly be drawn to originally filed claims 54-67, and 95-97.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 54, 55, 60-63, 95-97, and 101 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,505,695 to Eplett, Jr.

Regarding claims 54, 55, 60-63, 95-97, and 101, Eplett Jr. teaches a device for insertion in a human or animal body or body cavity (**figure 1**), the device having an inflatable and expandable means (**4**) containing a solution (**column 3 lines 24-25: antimicrobial fluid**) comprising at least one component capable of releasing at least one low molecular antimicrobial compound (LMAC), the LMAC having a molecular weight equal to or less than 250U and is capable of permeating into the adjacent tissue or body cavity and the at least one component releases the LMAC upon acidification (**refer to figures 1 and 3, abstract, and columns 1-4. Regarding lines 4-9 of claim 1 please note that it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138**); wherein the LMAC is released when the at least one component is

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contacted with a second component (**multiple layers (10) disclosed in column 2 lines 54-63; contact between elements 3 and 4 as shown in figure 1**); wherein the device is a catheter for insertion into the urinary tract of the human or animal body (**figure 1**) and the inflatable and expandable means comprise an inflatable cuff (**4**); wherein the cuff when inserted into the urinary tract is situated in the urinary bladder (**implied in column 2 lines 30-40**); a first end adapted to connect to a fluid collection device (**refer to figure 1 and note that it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138; for the case of a constituent of a solution, the Examiner once again states that the second component is not positively claimed and is part of functional recitation**); wherein the device is an intratracheal tube, a gastric tube, a vascular catheter, a vascular catheter port (**port shown best in figure 1**), and a wound drain tube (**regarding the aforementioned limitations, the device of Eplett, Jr. is a functional equivalent of each of these devices, the main requirement being that a urinary catheter is a tube which may function as a tube/catheter that may be placed within the vasculature, trachea, etc.**).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 56-59, and 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,505,695 to Eplett Jr. in view of U.S. Patent No. 6,425,881 to Kaesemeyer.

Regarding claims 56-59, and 64-66, Eplett Jr. teaches the limitations of claims 54, 55, 60, and 61 (**see above**), but does not explicitly teach wherein the at least one component is inorganic nitrite and the second component is ascorbic acid or acetic acid; a liquid being selected from the group consisting of water, saline or any physiological buffer, and wherein the LMAC is selected from the group consisting nitric oxide (NO), NO₂, N₂O₃, N₂O₄, HNO₃, HNO₂, NO⁺, NO⁻, O²⁻, O₃, singlet oxygen, H₂O₂, OONO-, HOONO, NOCl, NOSCEN, NO thiocyanate, an OH radical and HOCl. Kaesemeyer however, teaches wherein the at least one component is inorganic nitrite (**figures 1A and 1B, column 8 lines 33-44**) and the second component is ascorbic acid or acetic acid; liquid being selected from the group consisting of water, saline or any physiological buffer, and wherein the LMAC is selected from the group consisting nitric oxide (NO), NO₂, N₂O₃, N₂O₄, HNO₃, HNO₂, NO⁺, NO⁻, O²⁻, O₃, singlet oxygen, H₂O₂, OONO-, HOONO, NOCl, NOSCEN, NO thiocyanate, an OH radical and HOCl (**column 17 lines 4-27**). It would be obvious to one of ordinary skill in the art at the time the invention was made to modify the solution of Eplett Jr. with the solution of Kaesemeyer with the motivation of providing an alternate medicament to the patient as is well known in the art.

3. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,505,695 to Eplett Jr. in view of U.S. Patent No. 5,049,140 to Brenner et al.

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Regarding claim 67, Eplett Jr. teaches all of the limitations of claim 54 (**see above**), but does not explicitly teach a device having a concentration of one or more metal ions in the contents of the inflatable and expandable means or in the material or on the surface of the device, the concentration being sufficient to increase the antimicrobial effect. Brenner teaches a device having a concentration of one or more metal ions in the contents of the inflatable and expandable means or in the material or on the surface of the device, the concentration being sufficient to increase the antimicrobial effect (**Brenner: column 2 lines 35-48**). It would be obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Eplett Jr. with the concentration of metal ions as disclosed by Brenner with the motivation of providing an alternate antimicrobial surface/coating/solution as is well known in the art at the time of the invention.

Response to Arguments

4. Applicant's arguments filed 03/15/2010 have been fully considered but they are not persuasive.

In regard to the Applicant's arguments over the prior art reference of Eplett Jr, the Examiner asserts that Eplett Jr does teach each and every limitation of claims 54, 55, 60-63, 95-97, and 101 and the Examiner has shown above the rationale behind the rejection.

The Examiner has withdrawn the prior art rejections of Brenner and Ragheb, but has introduced a 103 rejection as necessitated by Applicant's amendment.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GERALD LANDRY II whose telephone number is (571)270-7409. The examiner can normally be reached on M-F, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/GEL/

Examiner, Art Unit 3763

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763